Module 7 – Implementation Issues

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Introduction

A common belief is that it is unnecessary to think about the implementation of the study until the study gets funded so the only worry is to get a scientific proposal together in time to send to the funding agency. If it gets funded, then it is time to worry about how to do it. Correct? Far from it. If you have not thought about the boring practical details prior to and during the writing of the protocol, then you are in danger of producing a plan that is totally impractical. The reviewers will recognize that in a jiffy. Even if they like your question, if they don't think you can do the study, they won't fund you.

Objectives

To understand the different steps that have to be undertaken before the first subject is enrolled, the activities required of the investigator during the study and the quality control required to ensure valid data and hence valid results.

At the end of this module, you will be able to:

- Recognise what needs to be done for your research project to satisfy ethics and hospital review boards
- Decide what staffing, including appropriate qualifications will be required to run the project
- Determine what supplies will be needed
- Recognise what health care services will be required, such as laboratory, pharmacy, imaging, health records
- Develop a budget that will pay for all of the personnel, services and supplies
- Develop a time line to ensure that the study proceeds according to the plan necessary to achieve results
- Check whether the proposed project will be feasible in one centre or whether it will require multi-sites.

Key Concepts

- Ethics – tri-council guidelines
- Staffing requirements

- Supplies
- Services required
- Budget
- Justification of budget
- Timeline

Activities

- Reread your question(s)
- Write an ethics submission (eg. for UBC)
- Work out how much staffing is required for your project
- Calculate the supplies required for your project
- Indicate whether pharmacy and laboratory services will be required
- Work out how data management is to be achieved
- Calculate a budget for your project
- Draw a timeline

Quick Links

- Hulley SB, Cummings SR. "Designing Clinical Research: An epidemiological approach, chapter 3.
- UBC Ethics http://www.bcricwh.bc.ca/research_support/forms/ubc_review.htm
- Children's & Women's of B.C. Research Review Board http://www.bcricwh.bc.ca/research_support/forms/cw_review.htm
- National Council on Research Ethics – Compendium of Ethics Guidelines
- See our "Extra Resources" page for more examples of Consent Forms, Budgets, Timelines, and IRB applications.

Module 7: Implementation Issues

Background

A common belief is that it is unnecessary to think about the implementation of the study until the study gets funded so the only worry is to get a scientific proposal together in time to send to the funding agency. If it gets funded, then it is time to worry about how to do it. Correct? Far from it.

If you have not thought about the boring practical details prior to and during the writing of the protocol, then you are in danger of producing a plan that is totally impracticable. Not only that, you will not convince the funding agency reviewers that you know what you are doing and you will be less likely to get funded. Even worse than that, you are highly likely to produce a simplistic budget that is totally insufficient. Trying to write a budget while sitting in your armchair in front of the TV is like being an armchair coach for hockey - you think that you know what you are doing. However, you are likely to have underestimated the time that study activities and services will consume. Of course, that is the very time that you get funded and then you are left having to do many of the chores yourself just to get the study done! And you know you don't have time for that.

Now you can guess what is coming next. Think about all of the processes that are required to conduct the study WHILE you are planning it. That way, if you think that you need two MRIs per patient for the skateboard injury study, a quick assessment of the cost and the feasibility of getting your imaging department to read the MRI s and you will quickly decide to reduce it to one or rely on X-rays instead.

Assignment

The following sections cover each of the steps to be considered as you write your protocol with a guide to the practical solution for each step, using Vancouver Children's and Women's hospitals, and UBC as guides for the costing and availability of resources for research. If you are writing a protocol to be conducted elsewhere, the steps will be similar but not the same and you will have to get help from these institutions to answer your questions. However, the questions will be the same. Whether you are using questions from your own clinical experience or trying to develop one from the Belltown examples, the same information will have to be used for both. Examples for each step can be found in the assignment section.

To demonstrate that you understand the steps in implementation, you are asked to write out a study plan, including the types and number of services required, what personnel you think that you will need and provide a budget that you think will be reasonable to conduct the study. In addition, it will be helpful to you to develop a time line for the study since this guides the budget and helps you to recognize if your plan is feasible.

Your additions to the protocol should be reviewed by your mentors.

Interactive Session: Steps in Implementation

Ethics

Research in human subjects requires that you, the investigator, and the institutions you work in think carefully about the ethical concerns of the study being proposed and you need to demonstrate that you have put into place procedures and checks that will protect the subjects who are willing to be part of the study. Once more, this is a topic that should be considered long before you reach the stage of funding, since no funding agency will release funds to you unless your proposal has received ethical review and approval in your home institution. You will hear horror stories about trying to get ethics approval, but, if you follow the guidelines, it becomes less of a nightmare.

To help you to understand the ethical principles governing human research, there have been several different documents outlining these principles. In Canada, the recommended document that guides human research is the Tri-Council Policy statement (http://www.cs.ualberta.ca/~wfb/ethics/ethics-e.pdf) entitled Ethical Conduct for Research Involving Humans , developed by the three major funding agencies: Canadian Institutes of Health Research (CIHR), the Social Sciences and Humanities research council (SSHRC) and National Sciences and Engineering research council (NSERC). This document is used by the human ethics committee at the university to guide the review of each proposal. To assist in this review, there is an ethics application form(http://www.ors.ubc.ca/ethics/index.htm) to be completed by you which will cover all the procedures that you are going to do, the risks and benefits to the individual, how you are going to protect the identity. Finally the committee will want to see a consent form (http://www.ors.ubc.ca/ethics/clinical/c-forms.htm) (and in the case of research in children, an assent form).

In Vancouver, unlike other institutions, the university ethics board is separate from the hospital review board. In the past this has led to a great deal of confusion since both committees seemed to conduct the same type of review and frequently there were gaps. Now, this procedure has been

revised and the UBC committee will only look at ethics and the hospital committee will look at scientific soundness (methodology) and the effects on resources used in the hospital. e.g if you are asking for extra blood samples, these will not be paid for by MSP and the hospital has to decide whether the extra staffing needed can be accommodated. Of course, there is another Hospital Review (http://www.cfri.ca/research_support/forms/hospital_research_review.asp) form to complete. If you follow each step carefully, the task is tedious but not difficult.

Now try to develop a UBC ethics form for your proposal.

Staffing

With new investigators, there is a tendency to assume that the whole study can be conducted by the health care staff already caring for the subject, be it nurse, clinician, physiotherapist or pharmacist or that the laboratory will conduct all the tests as usual. Wishful thinking! Even if the staff involved in the care was willing, most services are already overworked and to ask for extra help is inappropriate. The other reason not to ask busy clinic staff is that the protocol takes second place and frequently procedures get missed, and your study becomes worthless.

If you are trying to conduct a study without funding, this may be your scenario. However, if you are going to submit your proposal to a granting agency, you have the opportunity to ask for appropriate staff to conduct the study. How do you decide what is appropriate? The easiest way for any researcher (new or established) is to WALK yourself through the different steps of the study. Even better, think about one of your next patients as a potential subject. Even although you are not doing all the study procedures, make a note to yourself about the time taken by each staff member, the procedures that have to be done and then remember that in the research study itself, there will be extra time required to ask for consent and keep track of the data collected. Using this information, decide how long it took to care for a patient, which staff was involved at each step and then extrapolate from that one subject to the whole study. This is also a useful exercise for seeing what data need to be collected and how.

Justification: When you add staffing to your budget in your research submission, you will have to justify why each person is required. Having done your "walk through" this will become much easier.

Now try to develop a staffing requirement, with justification, for your own question.

Supplies

As with staffing, you cannot assume that you can use all hospital supplies for your study. Hospitals are not given budgets to conduct research. So what do you do? As with the staffing, note what

supplies you have used at each step of caring for the "pretend" subject. If the supplies were used for normal care then you do not need to count these, but if you have added extra steps, then these do need to be counted. "Supplies" usually encompass clinical supplies such as test kits, bandaids, splints and office supplies such as paper, xeroxing, computer toner, telephone courier charges.

Now try to develop a list of supplies, with justification, for your own question.

Services

An assessment of extra services required follows the same path. If your protocol includes normal clinical services, and there is nothing extra (you are observing normal care) then you don't need to add clinical services. However, if you are going to ask for extra blood then you will need to count the tubes, and count the laboratory time for these extra procedures. You can go the Laboratory research representative who has been given the position of helping researchers work through this part of the proposal. Likewise, there is a Pharmacy research representative if you need drugs dispensed through the pharmacy. For all other supplies, however, such as the extra MRIs mentioned before, you will have to negotiate with the appropriate department to see if a) it can be done and b) how much it will cost. Other services such as data management and statistical analyses should also be included here. Don't assume that you are going to do this yourself in your spare time – you don't have any. As with the staffing and supplies, you will need to justify why you need the extra services and why they cost that much.

Now try to develop a list of services, with justification, for your own question.

Budget

By this stage, in the implementation of your protocol, you should have all the steps required to prepare your budget. Once more, think through from the beginning to the end of your protocol and decide if you have sufficient staff, adequate supplies and have approached the service providers whose help is essential to the success of your study.

Now try to develop a budget, with justification, for your own question.

Timeline

One of the steps frequently overlooked but critical to making sure your budget is adequate is to form a timeline for the study. Now that you have walked through one patient and know how long it will take, the next question to answer is whether the patient supply is there. Do you see 10 skateboard injuries a week or one every two days. Take that number, calculate how long the study will last if everyone consents, and then multiply that time by at least 2 (probably 3) since not all subjects

approached will consent to be in the study. Next, remember that the study will not start enrolling on the first day that you get the money. There is some "up front" activity to get the financial arrangements made with UBC or the Hospital, the forms have to be xeroxed or printed and you have to spend time explaining to everyone. In the clinic service exactly what is going to happen so that you get cooperation.

After the last patient has been enrolled, there is a lag until these data are collected and then data have to be entered and analysed before the study is considered to be over.

Now try to develop a timeline for your own question.

Summarize your Progress

At this point you can round out the protocol with the implementation details. If your question is complex, most reviewers would prefer to see a good chunk of the protocol being used to show how the study will progress rather than an extra page on review of the literature. This whole section shows how much thought you have put into the study and this tends to allay fears that you may not be ethical or that you may be sloppy in your study conduct, both guaranteed to kill your application.

Assignment

1. To demonstrate that you have learned from the module, you are asked to:
    - complete an ethics submission form
    - complete an informed consent document
    - write a budget and justify each item on the budget
    - draw up a timeline for the conduct of the project.
2. (Optional) Review the implementation strategies for each of the following protocols and critique the strengths and weaknesses